

**REMARKS**

Reconsideration and further examination of the application are requested. All objections and rejections are respectfully traversed.

**Election/Restriction**

Applicant respectfully requests reconsideration of the determination that newly added claims 15-21 are independent and distinct from elected claims 4-14. Newly added claims 15-21 are computer-readable medium claims reciting a plurality of instructions. As shown in the following table, moreover, the recited instructions of newly added claim 15 are directly related to the steps recited in elected method claims 4 and 9.

<u>Claim 4</u>	<u>Claim 9</u>	<u>Claim 15</u>
A method executed in a computer system having at least one processor for determining axial rotation of a pelvis from a single fluoroscopic image, comprising	A method executed in a computer system having at least one processor for determining the transaxial rotation of a pelvis from a single fluoroscopic image, comprising	A computer-readable medium comprising instructions executable by at least one processing entity for determining a patient-specific pelvic coordinate system from a single near AP intra-operative image of the patient, the medium comprising:
A. receiving a fluoroscopic image of said pelvis in the near AP direction;	A. receiving a fluoroscopic image of said pelvis in the near AP direction;	instructions to receive a single intra-operative fluoroscopic image of the patient's pelvis in the near AP direction;
B. defining first and second landmarks of said pelvis on said image, said landmarks separated from each other in at least an anterior-posterior direction;	B. defining first and second landmarks of said pelvis on said image, said landmarks separated from each other in at least an anterior-posterior direction;	instructions to define first and second landmarks of said pelvis on said image, said landmarks being separated from each other in at least an anterior-posterior direction;

C. determining the transaxial displacement of said landmarks on said image; and		instructions to determine the transaxial displacement of said landmarks on said image;
	C. determining the axial displacement of said landmarks on said image; and	instructions to determine the axial displacement of said landmarks on said image;
D. using said displacement to determine the axial rotation of said pelvis with respect to the plane of said fluoroscopic image.		instructions to calculate an axial rotation of said pelvis with respect to the plane of said image based on the transaxial displacement, and
	D. using said displacement as a measure of the transaxial rotation of said pelvis with respect to the plane of said fluoroscopic image.	instructions to calculate a transaxial rotation of said pelvis with the respect to the plane of said image based on the axial displacement.

Accordingly, the newly added computer-readable medium claim 15 is connected in operation to elected claims 4 and 9. *See* MPEP §806.06. In addition, Applicant submits that patent applications routinely include both method claims and corresponding computer-readable medium claims without raising election/restriction issues. Accordingly, Applicant requests that the determination that newly added claims 5-15 are independent and distinct from elected claims 4-14 be withdrawn.

### §103

Claims 4-14 stand rejected under 35U.S.C. §103(a) based on U.S. Pat. Publ. No. 2004/0254586 to Sarin et al. (“Sarin”) in view of WIPO International Publ. No.

WO02/062248 to Chen et al. (“Chen”). Applicant respectfully disagrees.

Claim 1, in relevant part, recites as follows:

“determining the transaxial displacement of said (pelvic) landmarks on said image (of the pelvis)” and

“using said displacement to determine the axial rotation of said pelvis with respect to the plane of said fluoroscopic image”

Neither Sarin nor Chen discloses either of these steps.

While Sarin is directed to hip replacement or arthroplasty, it teaches an **image-free** technique. Specifically, Sarin discloses a back rest assembly (element 200) and a support assembly (element 212) that lock the patient in a fixed position on the operating table. Sarin at ¶[0047] (“The back support assembly is then added, *sandwiching* the patient between the back support and the support assembly”). The support assembly includes a touch plate (element 250) that has three touch points that correspond to anatomical points on the patient’s pelvis. Sarin at ¶[0037]. At no point does Sarin ever take any images of the patient’s pelvis, nor does Sarin ever determine the displacement of any landmarks from an image. Instead, Sarin’s approach, as with his earlier patent, is directed to an image-free surgical technique. Sarin at ¶[0008] (noting that Sarin’s earlier patent also describes an “image free, computer assisted navigation” system).

Chen also fails to disclose the recited claim elements. With Chen, the patient must be precisely positioned on the operating table so that there is **no rotation** of patient’s pelvis. Specifically, Chen states:

For an accurate definition of the frontal plane of the human pelvis, it is preferred that both anterior superior iliac spine landmarks 66 and 68 are on the same height level in the anterior posterior and in the sagittal planes, and that the landmark on the pubic symphysis 66 is centered in the anterior posterior plane, as depicted in Figure 2..

Chen, at p. 12; 22-26. With the patient positioned such that there is no rotation of the pelvis, the physician, using a tracked probe, registers the location of three anatomical landmarks in a computer-based, surgical navigation system. Chen, at p. 12; 27-30. An X-ray image of the pelvis is then taken and superimposed over a display of the digitized locations of the three anatomical landmarks, which were taken with the tracked probe. Chen, at p. 13; 6-20. Chen's computer system then allows the physician to adjust the digitized locations on the display screen, e.g., up, down, left, or right, so that they line up exactly with the anatomical landmarks shown in the X-ray image. *Id.* As with Sarin, there is no disclosure by Chen of determining any transaxial displacements on the image, nor is there any disclosure of determining axial rotation from such measured transaxial displacement.

Because the cited references fail to disclose at least two of the recited elements of claim 1, the combination of these references fails to result in Applicant's claimed invention. Furthermore, both Sarin and Chen actually teach away from the present invention. In particular, as discussed above, Sarin discloses an image-free technique, which he notes are less complex and less expensive than image-based techniques. Sarin, at [0008] ("The disclosed [image free] methods are less complex and expensive than reliance on radiological imagery."). In other words, Sarin discourages the use of image taking as it adds complexity and expense. Chen positions the patient precisely on the operating table so that there is not axial rotation of the patient's pelvis. Chen, at p. 12; 22-26. That is, Chen teaches against positioning the patient such that there could be any rotation of his or her pelvis.

Accordingly, for the reasons set forth herein, Applicant requests that the rejection of claim 1 be withdrawn. Independent claim 9 recites:

“determining the axial displacement of said landmarks on said image,”  
and

“using said displacement as a measure of the transaxial rotation of said pelvis with respect to the plane of said fluoroscopic image.”

Claim 9 is thus distinguishable over the cited references for at least the same reasons as set forth above in connection with claim 1. Claims 2-8 and 10-14 depend from claims 1 and 9, respectively, and thus they too are distinguishable over the cited references.

Applicant further notes that, while Chen was also asserted during prosecution of the counterpart European Patent Application (Ser. No. 04776221.6), that application has since been allowed as EP Pat. No. 1625890.

Applicant submits that the application is in condition for allowance and early favorable action is respectfully requested.

Please charge any additional fee occasioned by this paper to our Deposit Account No. 03-1237.

Respectfully submitted,

/Michael R. Reinemann/  
Michael R. Reinemann  
Reg. No. 38,280  
CESARI AND MCKENNA, LLP  
88 BLACK FALCON AVENUE  
BOSTON, MA 02210  
Telephone: (617) 951-2500  
Facsimile: (617) 951-3927